UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,229	06/25/2001	Richard Ian Christopherson	650061.401USPC	2287

500 7590 08/27/2009

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 5400
SEATTLE, WA 98104

EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
08/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/869,229	CHRISTOPHERSON ET AL.	
	Examiner	Art Unit	
	Carolyn Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58,71 and 73-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58, 71, 73-77* is/are rejected.

7)☒ Claim(s) *78-83* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks, filed 6/3/09, are acknowledged. Amended claims 58, 71, 73-77 and new claims 78-83 are acknowledged.

Applicant's arguments, filed 6/3/09, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 58, 71, and 73-83 are herein under examination.

Claim Objections

Claims 78-83 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. Claims 78-83 depend from claims 58 and 28. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 58, 71, and 73-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over the abstract of Gruber et al (Journal of Immunological Methods, 1993, Vol. 163, pp. 173-179) in view of Wysocki et al.(PNAS, 1978, Vol. 75, pp. 2844-2848) and Delamarche et al (Science, 1997, Vol. 276, pp. 779-781). This rejection is maintained and reiterated for reasons of record.

Gruber teaches the detection of the cell surface markers of CD3, CD4, CD8, CD14, CD19 and CD56. Gruber describes analysis of leukocytes in an individual with labeled monoclonal antibodies yielding quantitative and qualitative results on various lymphocyte

subpopulations to monitor leukemia. The abstract does not teach the use of a solid support comprising said immunoglobulin molecules or pattern binding or covalent binding.

Wysocki et al. teach that lymphocytes from a heterogeneous population can bind directly and indirectly to a polystyrene solid support coated with an antibody specific for a cell surface antigen, including fractionating, detecting and separating T and B lymphocytes (page 2844, first column, second and third paragraphs, abstract; page 2845, col. 1, fourth and fifth paragraphs; page 2848, col. 1, first paragraph). Wysocki et al. describe polyclonal antibodies (page 2844, col. 1, last 3 paragraphs to col. 2, first 6 paragraphs), as stated in instant claim 74. Wysocki et al. describe using Fab fragments (page 2844, col. 2, fourth paragraph), as stated in instant claim 76. Wysocki et al. teach that this method is a simple and inexpensive alternative to flow cytometry (page 2844, first column, second and third paragraphs). Wysocki et al. do not teach pattern binding or covalent binding.

Delamarche et al teach a method of applying different immunoglobulins in a pattern on a solid support with high resolution and glass and polystyrene (page 779, column 1 and column 2; and page 780, col. 1, last 2 paragraphs and Figure 2 caption, abstract). Delamarche et al. describe molecules being immobilized via covalent binding to the solid support (page 779, col. 3, second paragraph; page 781, col. 2, second paragraph), as stated in instant claim 71. Delamarche et al. describe immunoglobulins are patterned on substrates confined to specific areas (abstract), binding immunoglobulins specific for each region (page 780, col. 2, second paragraph), and a patterning step that is local with exposure of biomolecules to the surface that occurs only on targeted areas without cross interferences (page 781, col. 2, second paragraph). Delamarche et al teach that the method is inexpensive and has high spatial definition and is inherently general, so

that many assays in current use can be readily miniaturized without the need for lithographic equipment (page 781, second column).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a solid support as taught by Wysocki et al. comprising the immunoglobulin molecules CD3, CD4, CD8, CD14, CD19, CD56 as taught by Gruber wherein the motivation would have been to bind leukocytes from whole blood to antibodies bound to a solid support which was simple and inexpensive, as stated by Wysocki et al. (page 2844, first column, lines 6-13 after the abstract). It would have been further obvious to make patterns on a derivatised solid support as taught by Delamarche et al. in the method and device of Gruber and Wysocki et al. wherein the motivation would have been to providing an antibody array with high spatial resolution which is economical to produce and compatible with many existing chemistries and substrates already used to attach macromolecules to substrates, as stated by Delamarche et al. (page 781, col. 2, second paragraph).

Thus, Gruber in view of Wysocki et al. and Delamarche et al. make obvious instant claims 58, 71, and 73-76.

Applicant summarizes the instant invention. Applicant mentions application 09/888959 which was allowed by another Examiner. Applicant is reminded that each application is examined under its own fact pattern. Applicant argues the pending claims recite "each [immunoglobulin or antigen binding fragment thereof] being specific for a single cell surface marker presented only once in the array". It is noted that the portion in brackets is not recited in

the claims. It is also noted that "each" may refer to "immunoglobulin or antigen binding fragment thereof" or "discrete regions" or some other scenario in the last portion of instant claim 58. Applicant argues that Gruber detects cell surface markers of CD3, CD4, CD8, CD14, CD19, and CD 56, but relies on a completely different technique of flow cytometry. It is noted that Gruber is not relied on for every limitation which is why this is a 35 USC 103 rejection, not a 35 USC 102 rejection. Wysocki et al. teach that the solid support method is a simple and inexpensive alternative to flow cytometry (page 2844, first column, second and third paragraphs). Applicant argues that Gruber does not disclose any subset of CD markers for diagnosis of T cell, B cell, or myeloid lineage. It is noted that Gruber is not relied on for every limitation which is why this is a 35 USC 103 rejection, not a 35 USC 102 rejection. Wysocki et al. and Delamarche et al. describe using solid supports. Wysocki et al. teach that lymphocytes from a heterogeneous population can bind directly and indirectly to a polystyrene solid support coated with an antibody specific for a cell surface antigen, including fractionating, detecting and separating T and B lymphocytes (page 2844, first column, second and third paragraphs, abstract; page 2845, col. 1, fourth and fifth paragraphs; page 2848, col. 1, first paragraph). Wysocki et al. teach that this method is a simple and inexpensive alternative to flow cytometry (page 2844, first column, second and third paragraphs). In response to applicant's argument that Gruber does not teach the intended use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant argues that Wysocki et al. do not describe characterization of cells as a pattern of cell binding. It is noted that Wysocki et al. are

not relied on for every limitation which is why this is a 35 USC 103 rejection, not a 35 USC 102 rejection. Delamarche et al. describe immunoglobulins are patterned on substrates confined to specific areas (abstract), binding immunoglobulins specific for each region (page 780, col. 2, second paragraph), and a patterning step that is local with exposure of biomolecules to the surface that occurs only on targeted areas without cross interferences (page 781, col. 2, second paragraph). Applicant argues that Delamarche et al. do not disclose extensive profiles of cell surface molecules as a diagnostic tool. It is noted that Delamarche et al. are not relied on for every limitation which is why this is a 35 USC 103 rejection, not a 35 USC 102 rejection. Delamarche et al. provide immobilized ligands on surfaces which is the first step in many bioassays (page 779, col. 1, first paragraph). Gruber and Wysocki et al. provide diagnostic tools. Applicant cites In re O'Farrell which involves "obvious to try" arguments. It is noted that the rationale for 35 USC 103 rejections above include motivational statements from the references themselves which supports the prima facie case of obviousness. Applicant states that secondary factors must be evaluated in obviousness rejections. Applicant argues the Examiner was provided with a press release where the applicant's licensee received an award which demonstrates commercial success. It is noted that secondary considerations are not enough. Applicant must show non-obviousness (i.e. persuasive arguments against 103 rejection) in combination with sufficient evidence of secondary considerations (see MPEP 2145).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over the abstract of Gruber et al (Journal of Immunological Methods, 1993, Vol. 163, pp. 173-179) in view of Wysocki et al.(PNAS, 1978, Vol. 75, pp. 2844-2848) and Delamarche et al (Science, 1997, Vol. 276, pp. 779-781) as applied to claims 58, 71, and 73-76 above, and further in view of Dano et al. (US 5,519,120). This rejection is maintained and reiterated for reasons of record.

Gruber et al in view of Wysocki et al. and Delamarche et al. teach the limitations of instant claims 58, 71, and 73-76. They do not describe a nitrocellulose-coated glass slide.

Dano et al. describe a nitrocellulose-coated glass slide and using various antibodies, including monoclonal and polyclonal antibodies as well as using complexing agents such as

protein G to form a complex with immunoglobulins and link to a solid support (col. 17, second and third paragraphs; and col. 19, fourth to seventh paragraphs; col. 83, sixth paragraph).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a solid support as taught by Wysocki et al. comprising the immunoglobulin molecules CD3, CD4, CD8, CD14, CD19, CD56 as taught by Gruber wherein the motivation would have been to bind leukocytes from whole blood to antibodies bound to a solid support which was simple and inexpensive, as stated by Wysocki et al. (page 2844, first column, lines 6-13 after the abstract). It would have been further obvious to make patterns on a solid support as taught by Delamarche et al. in the method and device of Gruber and Wysocki et al. wherein the motivation would have been to providing an antibody array with high spatial resolution which is economical to produce and compatible with many existing chemistries and substrates already used to attach macromolecules to substrates, as stated by Delamarche et al. (page 781, col. 2, second paragraph). It would have been further obvious to use a nitrocellulose-coated glass slide as the derivatised solid support as taught by Delamarche et al. and in the method and devices of Gruber and Wysocki et al. wherein the motivation would have been to use any suitable material for detecting antibodies for therapeutic use and drug screening, as stated by Dano et al. (col. 1, second paragraph and col. 19, sixth paragraph) as well as providing an antibody array with high spatial resolution which is economical to produce and compatible with many existing chemistries and substrates already used to attach macromolecules to substrates, as stated by Delamarche et al. (page 781, col. 2, second paragraph).

Thus, Gruber in view of Wysocki et al., Delamarche et al., and Dano et al. make obvious instant claims 58, 71, and 73-77.

Applicant cites various paragraphs of Dano et al. Applicant argues that the passages fail to relate to leukemia, an array, or live cells are not captured. This statement is found unpersuasive as Dano et al. was not cited for these limitations, but rather a nitrocellulose-coated glass slide. It is noted that Dano et al. are not relied on for every limitation which is why this is a 35 USC 103 rejection, not a 35 USC 102 rejection. Applicant argues the Examiner should recognize the difference between piecemeal acquisition of a limited surface expression profile (Gruber), and the acquisition of a far more extensive profile in one assay device of the instant invention. This statement is found unpersuasive as the prior art describes the structural limitations of the device of the instant invention (i.e. device with a solid support and an array of immunoglobulin molecules or antigen-binding fragments which are specific for various cell surface marker antigens on a leukocyte) which renders the invention obvious. Applicant's arguments are deemed unpersuasive for the reasons given above.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. If you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, please call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

August 18, 2009

/Carolyn Smith/
Primary Examiner
AU 1631